

<b>Notice of Allowability</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	09/470,667	ASAKURA ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Malgorzata A. Walicka	1652	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--**

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to 08/14/03.
2. ☒ The allowed claim(s) is/are 4-8,10,11,13-19,23,24,26,27,29-31,33,34 and 36-38.
3. ☐ The drawings filed on \_\_\_\_\_ are accepted by the Examiner.
4. ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) ☒ All    b) ☐ Some\*    c) ☐ None    of the:
    1. ☐ Certified copies of the priority documents have been received.
    2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
    3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).
  - \* Certified copies not received: \_\_\_\_\_.
5. ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
  - (a) ☐ The translation of the foreign language provisional application has been received.
6. ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application. **THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.**

7. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
8. ☒ CORRECTED DRAWINGS must be submitted.
  - (a) ☒ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
    - 1) ☐ hereto or 2) ☒ to Paper No. 20.
  - (b) ☐ including changes required by the proposed drawing correction filed \_\_\_\_\_, which has been approved by the Examiner.
  - (c) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No. \_\_\_\_\_.

Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet.

9. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

**Attachment(s)**

- |  |  |
|--|--|
| 1 <input type="checkbox"/> Notice of References Cited (PTO-892)  | 2 <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3 <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                    | 4 <input type="checkbox"/> Interview Summary (PTO-413), Paper No. _____    |
| 5 <input checked="" type="checkbox"/> Information Disclosure Statements (PTO-1449), Paper No. <u>8</u> | 6 <input type="checkbox"/> Examiner's Amendment/Comment                    |
| 7 <input type="checkbox"/> Examiner's Comment Regarding Requirement for Deposit of Biological Material | 8 <input type="checkbox"/> Examiner's Statement of Reasons for Allowance   |
|  | 9 <input type="checkbox"/> Other _____                                     |

Response to Office Action including Amendment and Petition for Extension of time, filed on August 14, 2003 is acknowledged. Claim 32 is cancelled; new claims 37 and 38 are entered. Claims 13-16, 30-31 and 34-36 are amended. Claims 1-11, 13-31 and 32-38 are pending and are the subject of this Office Action.

### **Detailed Office Action**

#### **1. Restriction/election**

The examiner issued the first restriction requirement on May 29, 2001. In response, filed on August 02, 2001, Applicants elected, with traverse, Group II, comprising claims 4-8, and 10-16, directed to DNA of SEQ ID NO: 1 encoding alcohol and aldehyde dehydrogenase (AADH) enzyme, expression vectors, recombinant host, and recombinant production of the enzyme.

In her Office Action of August 28 2001, taking in to account Applicants' arguments, the examiner withdrew the previous restriction requirement and issued the FINAL restriction requirement quoted below.

- Group I: claims 1-3 and 9 drawn to an enzyme comprising a recombinant polypeptide having alcohol and aldehyde dehydrogenase activity, classified in class 435, subclass 190.
- Group II: claims 4-8, and 10-16, drawn to DNA encoding said enzyme, expression vectors, recombinant host, and recombinant production of the enzyme, classified in class 536, subclasses 23.2, 320.1 and 252.3.
- Group III: claims 17-19, 23-24 and 26-27, drawn to production of aldehyde, alcohol, and carboxylic acid in fermentor, classified in class 435, subclasses 41, 136, 138, and 148.

Art Unit: 1652

Group IV: claims 20-22, 25 and 28, drawn to production of aldehyde, alcohol and carboxylic acid by the enzyme in vitro, classified in class 435, subclass 138.

Inventions of Group II and III are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the product, DNA encoding the enzyme, expression vectors and recombinant host of Group II can be used to recombinantly produce the enzyme and not for the production of aldehyde, alcohol, and carboxylic acid in a fermentor as claimed in Group III.

Claim 4-8, 10-11, 13-16 are directed to an allowable product. Pursuant to the procedures set forth in the Official Gazette notice dated March 26, 1996 (1184 O.G. 86), claim 17-19, 23-24 and 26-27, directed to the process of making or **using** the patentable product, previously withdrawn from consideration as a result of a restriction requirement, are now subject to being rejoined. Process claim 17-19, 23-24 and 26-27 are hereby rejoined and fully examined for patentability under 37 CFR 1.104. Claim 1-3, 9, 20-22, 25 and 28, not directed to the process of making or using the patentable product, will not be rejoined.

## **2. Rejection withdrawal**

### *2.1. 35 U.S.C. 112, second paragraph*

Rejection of claims 13-15 and 36 for insufficient antecedent is withdrawn, because the claims have been amended. Rejection of claim 32 is moot, because the claim has been cancelled.

*2.2. 35 U.S.C. section 112, first paragraph*

Lack of written description and scope of amendment

Rejection of claims 30, 31 and 34 under 35 U.S.C. 112, first paragraph, made in the previous Office Action is withdrawn, because the claims have been amended. Rejection of claim 32 is moot, because the claim has been cancelled.

*2.3. 35 U.S.C. 101*

Rejection of claims 16 and 36 made in the previous Office Action, paper No. 20 is withdrawn, because the claims have been amended.

**3. Examiner's amendment**

(1) Please cancel claims 1-3, 9, 20-22, 25 and 28.

(2) Please amend claim 16 to read:

Claim 16. A process for producing a recombinant enzyme having an alcohol and aldehyde dehydrogenase activity comprising:

(a) culturing a host cell comprising an expression vector comprising a DNA molecule encoding a recombinant polypeptide having alcohol and aldehyde dehydrogenase activity and amino acid sequence with at least 80% identity to the polypeptide sequence of SEQ ID NO: 5 in an appropriate culture medium; and

(b) recovering the recombinant enzyme.

Art Unit: 1652

(3) In claims 17-19 and 23-24 replace "recombinant organism of claim 10" with "host cell of claim 10".

Authorization for this examiner's amendment was given in a telephone interview with Applicants' representative, Gonzalo Merino, on November 24, 2003.

#### **4. Allowance**


Claims 4-8, 10-11, 13-19, 23-24, 26-27, 29-31 and 33-34, 36-38 are allowed for reasons indicated in the previous Office Action, paper no. 13.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Malgorzata A. Walicka, Ph.D., whose telephone number is (703) 305-7270. The examiner can normally be reached Monday-Friday from 10:00 a.m. to 4:30 p.m.

If attempts to reach examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapura Achutamurthy, Ph.D. can be reached on (703) 308-3804. The fax phone number for this Group is (703) 305-3014.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionists whose telephone number is (703) 308-0196.

Malgorzata A. Walicka, Ph.D.  
Art Unit 1652  
Patent Examiner



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